Exhibit B

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327 MDL 2327** **JOSEPH R. GOODWIN U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: *Wave 1 Cases*	

Intentional Oxidation of Prolene Mesh

Supplemental Report of Dr. Shelby F. Thames

August 8, 2016

Plaintiff's experts have opined that the explant cleaning protocol (Figure 1) we developed and use during the examination of explant samples in this litigation, in some way, 'destroys oxidation carbonyls' should they exist. To prove unequivocally this does not occur, an exemplar Prolene mesh (Gynecare TVT device 810041B) was intentionally oxidized via exposure to ultra violet light. This involved ultraviolet (UV) light exposure of pristine Prolene for 500 hours in a Q-Lab Q-Sun Xe-3 Xenon Test Chamber. Oxidation was affected according to an established and accepted testing protocol, i.e. ASTM G 155[1]. Following the ASTM G 155 protocol chamber cyclic conditions were set to 4 hrs. "on", at 340 nm wavelength, 1.10 W/m^2 irradiation at 63°C, and 35% RH, using a daylight filter set, followed by 1 hr. off" (40°C and 35% RH).

Sample Name	1st Step	2nd Step	3rd Step	4th Step	5th Step	6th Step
	Distilled water soak 1h	Desiccation drying 1 h, Analysis Before Cleaning	Distilled water. Water bath (80˚C), 20h	NaOCl. Shaker, 30min	Distilled water. Rinse; soak 1h; Rinse	Desiccation drying 1 h, Analysis After Cleaning 1

Sample Name	7th Step	8th Step	9th Step	10th Step	11th Step	12th Step	13th Step	14th Step
	Distilled water. Water bath (80˚C), 20h	NaOCl. Ultrasonic bath, 1.5h	Distilled water. Rinse, ultrasonic bath 1h, rinse.	Desiccation drying 1 h, Analysis After Cleaning 2	Distilled water. Water bath (80˚C), 20h	NaOCl. Ultrasonic bath, 4h	Distilled water. Rinse, ultrasonic bath 1h, rinse.	Desiccation drying 1 h, Analysis After Cleaning 3

Sample Name	15th Step	16th Step	17th Step	18th Step	19th Step	20th Step	21st Step	22nd Step	23rd Step
	Distilled water. Water bath (80˚C), 20h	0.8 mg/ml Proteinase K. Water bath (58˚C), 20h	0.8 mg/ml Proteinase K. Ultrasonic bath, 2h	Distilled water. Rinse, ultrasonic bath 1h, rinse.	Desiccation drying 1 h, Analysis After Cleaning 4	Distilled water. Water bath (80˚C), 20h	NaOCl. Ultrasonic bath, 4h.	Distilled water. Rinse, ultrasonic bath 1h, rinse.	Desiccation drying 1 h, Analysis After Cleaning 5

Figure 1. Explant Cleaning Protocol

A sample size of approximately 10 mm x 10 mm of the exemplar TVT device, lot 810041B, as noted in Figures 2 and 3, was placed in the UV exposure chamber (Figure 4).

Figure 2. Exemplar Gynecare TVT Device 810041B

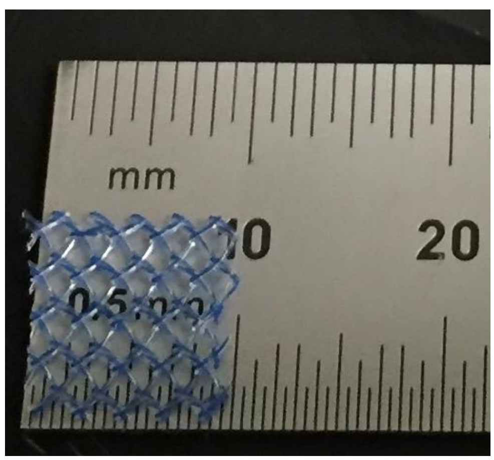

Figure 3. Exemplar TVT sample for UV exposure

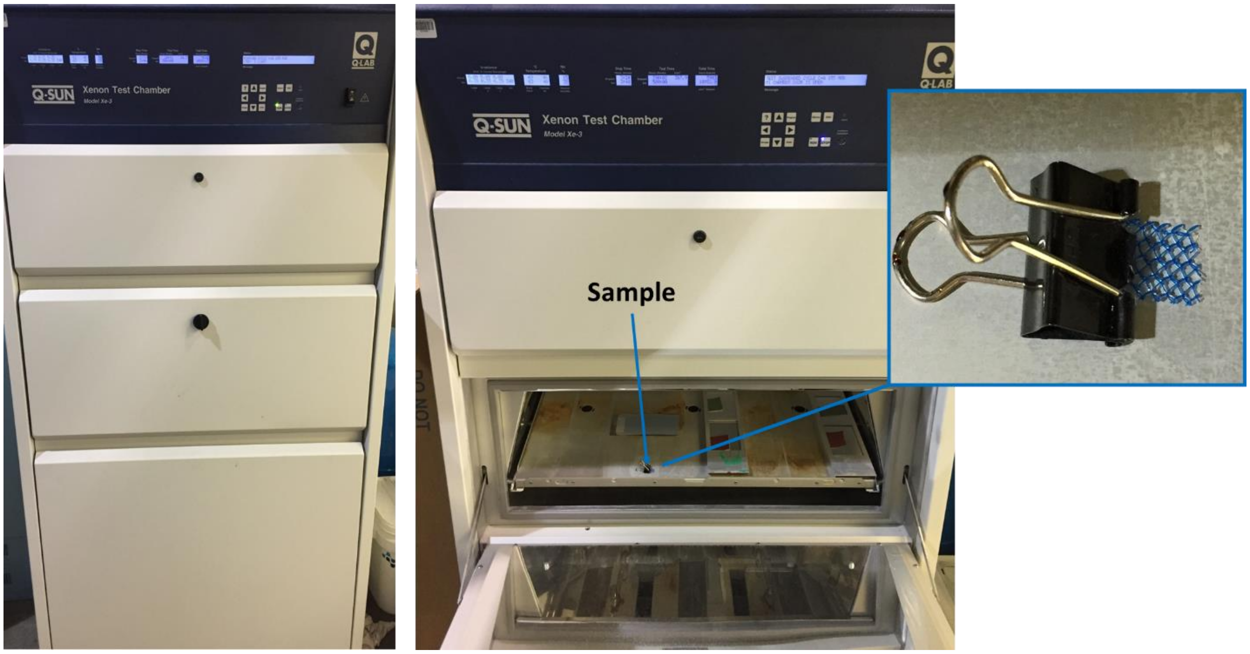

Figure 4. Q-Lab Q-Sun Xenon Test Chamber

The pristine exemplar TVT sample was characterized via Fourier Transform Infrared Microscopy (FTIR) with a Thermo-Nicolet Continuum FTIR Microscope (Figure 5) prior to UV exposure. The resulting spectrum (Figure 6) contains an inset image showing the penetrating IR beam location. The absorption frequency at 1742 cm^{-1}, indicative of Ethicon's DLTDP antioxidant, is also noted in my previous reports, which I rely upon, and is present in the spectrum.

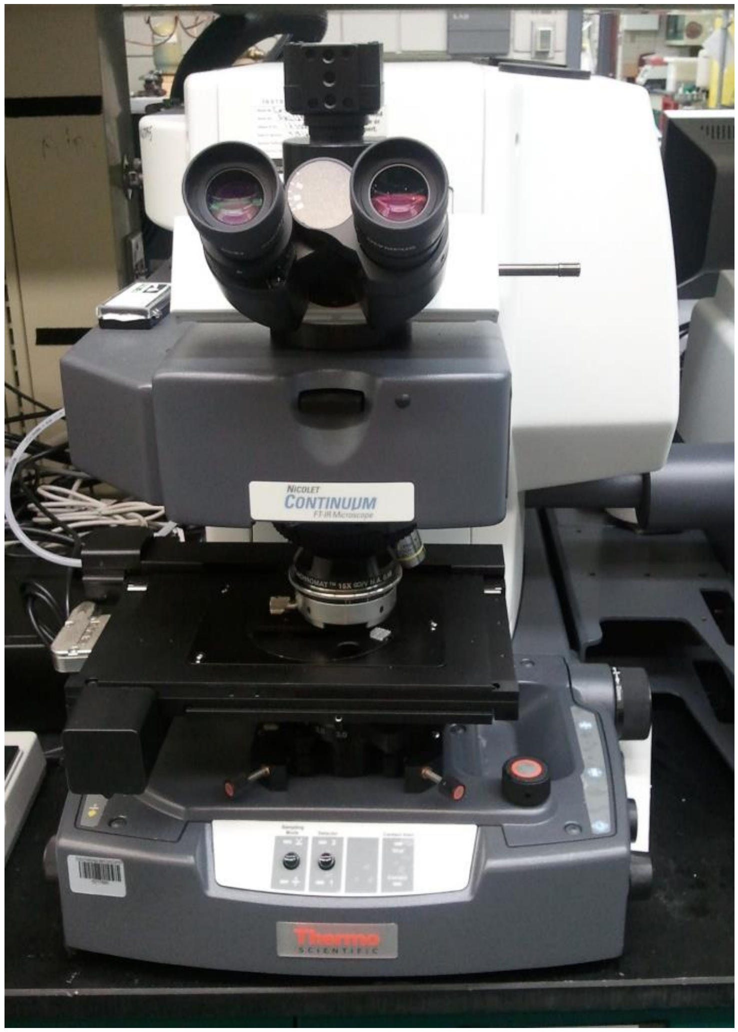

Figure 5. Thermo-Nicolet Continuum FTIR Microscope

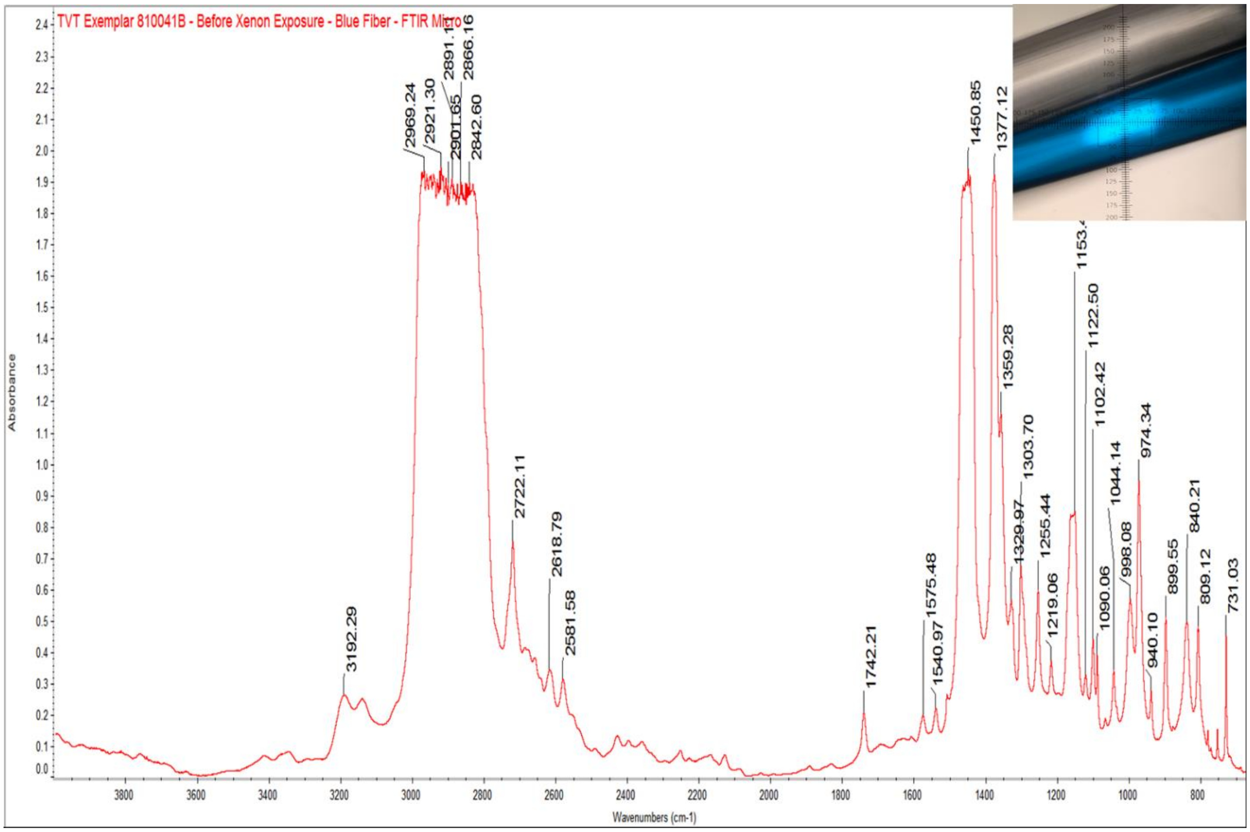

Figure 6. Pristine TVT Exemplar 810041B – Before Xenon Exposure – Blue Fiber

At 500 hrs. UV exposure the TVT exemplar was removed from the exposure chamber and again characterized via FTIR Microscopy (Figure 7). Oxidative degradation is noted as evidenced by the presence of strong carbonyl absorption frequencies in the ~1740 cm^{-1} to 1713 cm^{-1} region accompanied by extensive fiber cracking.

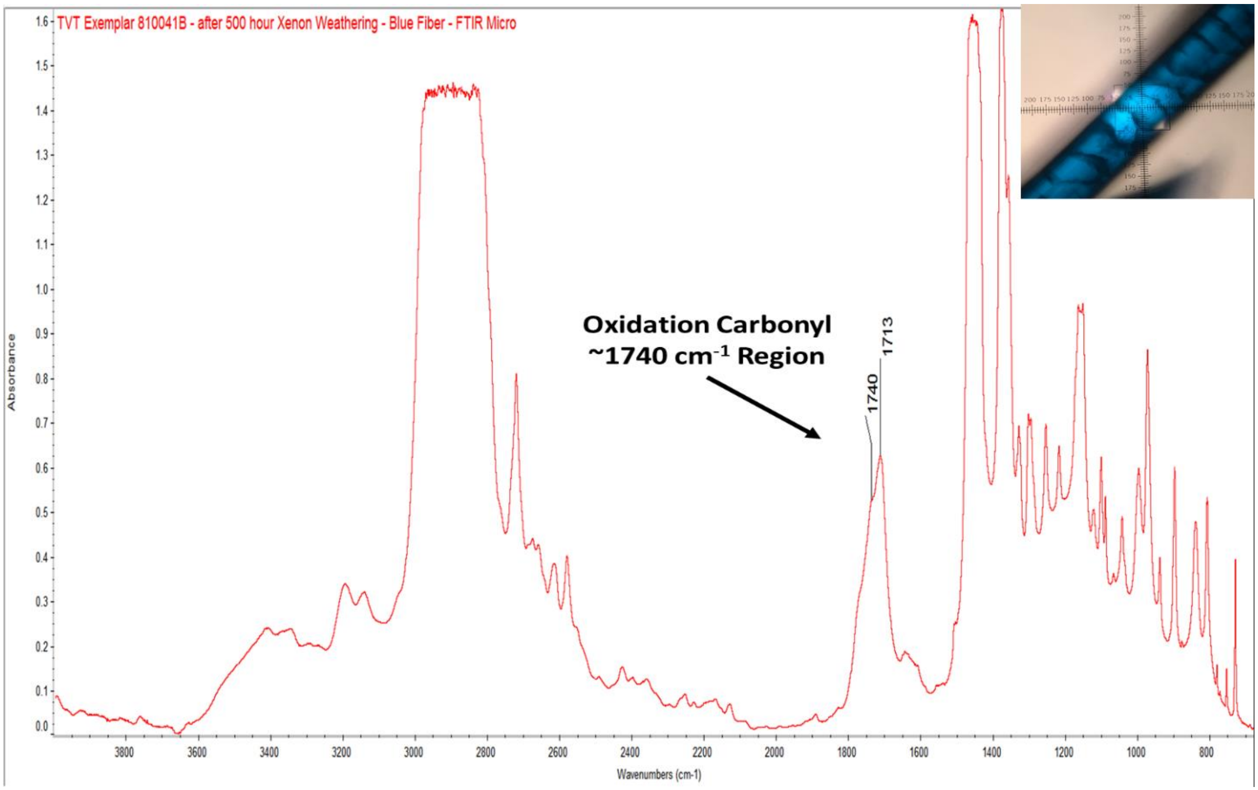

Figure 7. TVT Exemplar 810041B – After 500 hrs. Xenon Exposure – Blue Fiber

Plaintiffs have suggested the cleaning protocol removes the carbonyl oxidation product(s) of Prolene, yet they have absolutely no supporting evidence supporting their claim. In order to verify this did not and does not happen, we have begun to process the intentionally oxidized Prolene sample in the cleaning protocol (Figure 1).

The oxidized TVT exemplar (Figure 7) was immersed in 80°C water for 20 hours, removed, dried, and analyzed via FTIR microscopy (Figure 8 – red Spectrum). The oxidized TVT exemplar was then immersed in sodium hypochlorite solution (NaOCl) on a shaker for 30 minutes, removed, dried, and again analyzed via FTIR microscopy (green spectrum). Although there was no flesh present to utilize sodium hypochlorite's oxidizing capacity, the FTIR spectral overlay demonstrates that carbonyl (oxidation) absorption did not diminish during, and as a result of, the cleaning protocol (Figure 8). Thus, it is abundantly clear that should carbonyl oxidation of Prolene occur, the resulting carbonyl frequency, as shown herein, would be present in the FTIR spectrum of the oxidized Prolene sample.

To date, the cleaning protocol of Figure 1 did not remove oxidized carbonyl moieties from Prolene. Moreover, should oxidized Prolene be present it will be seen as a strong carbonyl frequency at or near ~1740 cm^{-1}.

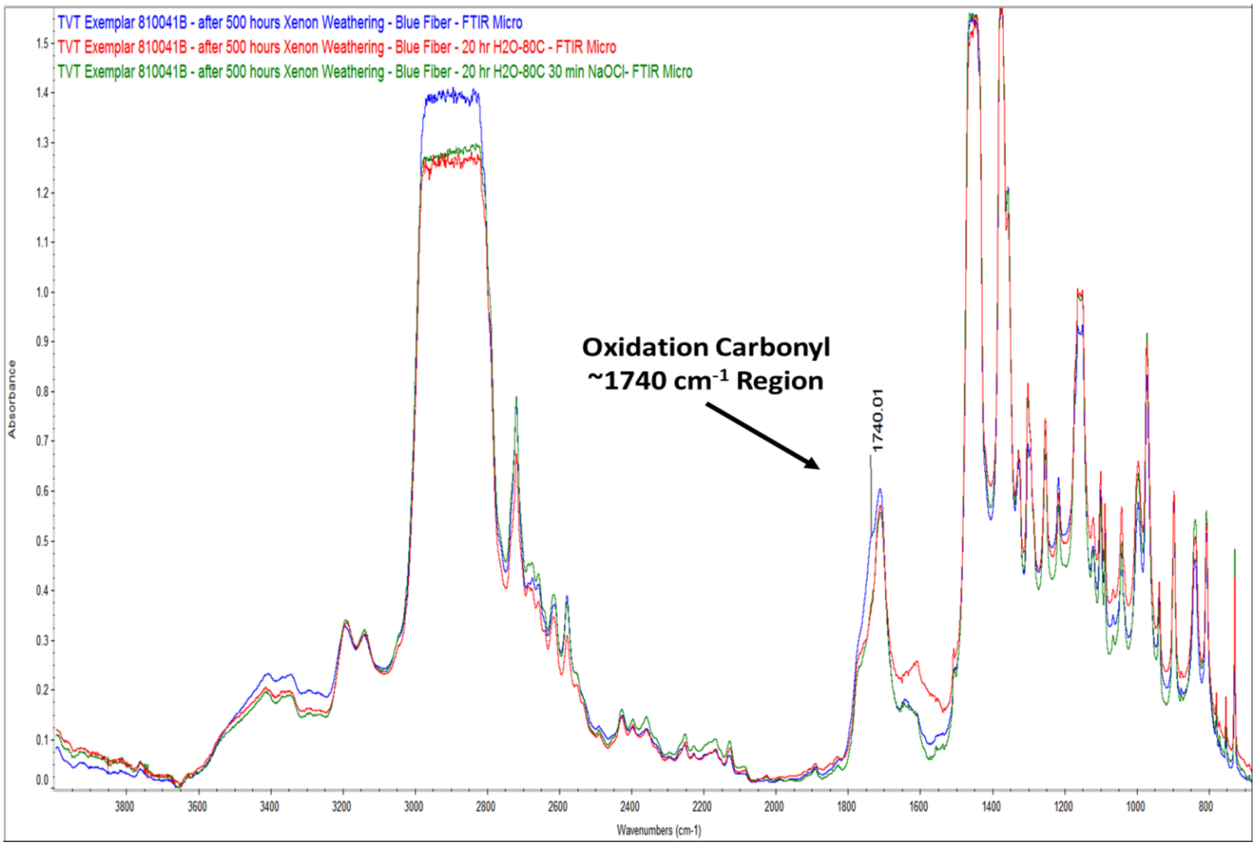

Figure 8. Overlay of Blue Fiber TVT Exemplar 810041B – After 500 hrs. Xenon Exposure (Blue Spectrum), After 20 hrs. Immersion in 80°C water (Red Spectrum), and After 30 min. Immersion in NaOCl (Green Spectrum)

Digital microscopy and scanning electron microscopy (SEM) of the before and after fiber exposure samples were conducted with a Keyence VHX-600 digital microscope (Figure 9) and a Zeiss Sigma VP FEG-SEM (Figure 10). One can readily observe the oxidation effects upon Prolene as demonstrated by light microscopy and SEM images (Figures 11 and 12) of fibers; before and after UV exposure. As a result of UV exposure as described herein, Prolene fibers were grossly embrittled and demonstrated deep cracks resulting in fiber rupture via crack propagation.

In summary, our prior reports and current experimental results prove Prolene does not degrade (oxidize) *in vivo*. Furthermore, the experimental results reported herein of the purposeful oxidation of Prolene is yet more proof that:

- Prolene does not oxidize *in vivo*, and
- the cleaning protocol (Figure 1) utilized does not remove oxidized Prolene should it exist on an explant.

- In the former instance, we have examined and tested approximately 50 explants, none of which have shown any indication of oxidation by FTIR,

SEM, or light microscopy examinations. In these cases, carbonyl absorption frequencies, known to accompany oxidized Prolene (see Figure 7) were not present, and thus *in vivo* oxidation did not occur.

Note the extensive fiber cracking and flaking: the product of crack propagation. Clearly the physical properties of Prolene have been severely compromised by UV light exposure (i.e. oxidative degradation).

Plaintiffs have posed the concept, without any scientific evidence, that our cleaning protocol (Figure 1) removes oxidation products formed and/or residing on Prolene's surface. However, purposeful oxidation of Prolene and subsequent cleaning proves unequivocally our process does not remove oxidized Prolene if it is present. When or if oxidized Prolene is present, as we have shown herein, it is evidenced by strong carbonyl absorption frequencies (Figure 8)[2]. The carbonyl group(s) responsible for the strong absorption are not removed by cleaning.

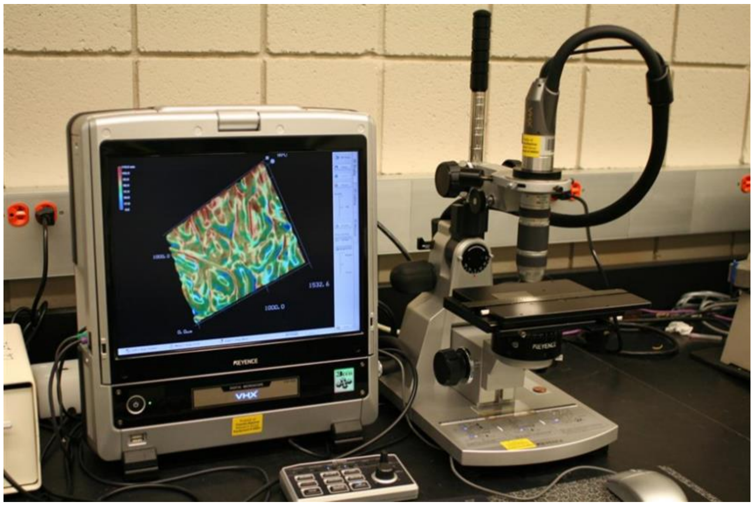

Figure 9. Keyence VHX-600 Digital Microscopy System

Figure 10. Zeiss Sigma VP FEG-SEM

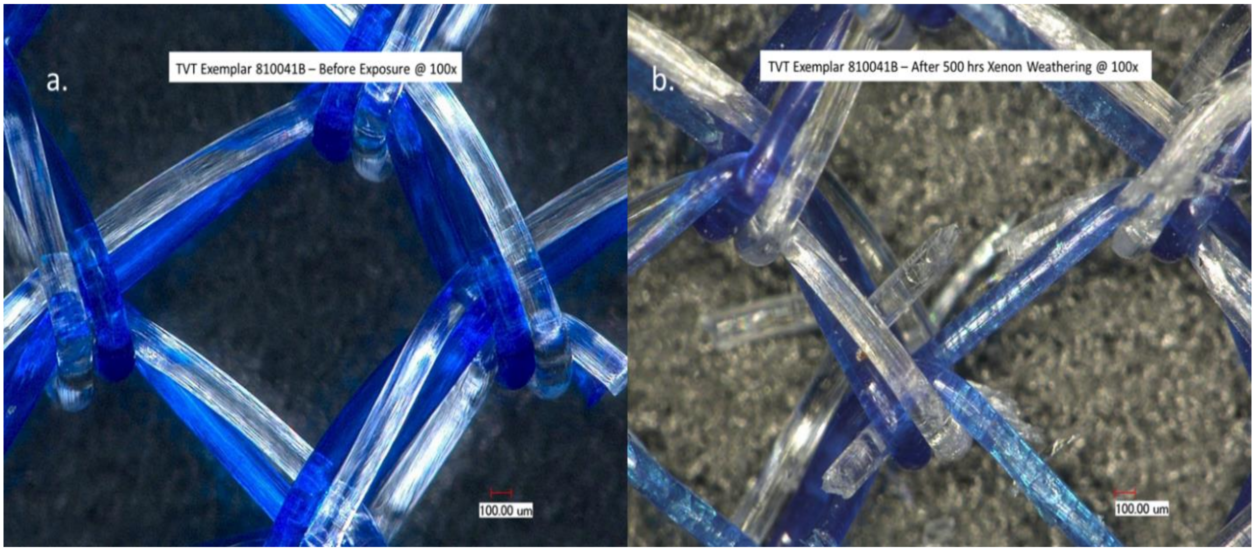

Figure 11. Light Microscopy of TVT 810041B Exemplar before UV exposure (a.) and after 500 hrs. UV exposure (b.)

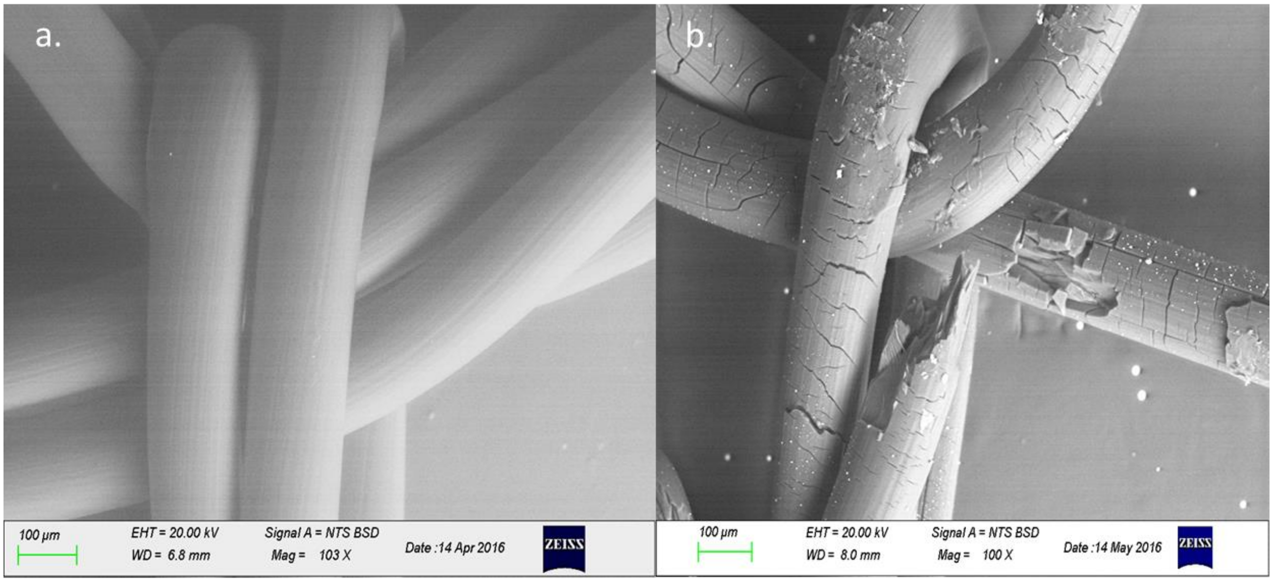

Figure 12. SEM of TVT 810041B Exemplar before UV exposure (a.) and after 500 hrs. UV exposure (b.)

The oxidized Prolene exemplar is currently being processed through the cleaning steps of Figure 1, and that data will be reported when complete. At this writing we have completed steps 1 through 4 and these data are reported herein. Our experience to date has shown these first 4 steps to be those during which the majority of the proteins are removed, and if there is Prolene oxidation these are the steps where oxidation would most likely be observed.

I reserve the right to supplement this initial report and analysis, create additional exhibits as necessary to illustrate my testimony based upon the receipt of additional information, documents and materials, and to revise this report following the receipt of additional information and/or materials that have not yet been made available.

Shelby F. Thames, Ph.D.

[1] ASTM G155 – Standard Practice for Operating Xenon Arc Light Apparatus for Exposure of Non-Metallic Materials
[2] Stuart, Barbara, H. (2004) Infrared Spectroscopy: Fundamentals and Applications, Analytical Techniques in the Sciences, ISBN: 9780470854280, Wiley

Xenon Weathering of Prolene Exemplar

April 12, 2016 – An approximately 10 mm x 10 mm exemplar Prolene mesh (Gynecare TVT device 810041B, Lot #3694576) was cut from an exemplar TVT device previously received on September 20, 2013 from Exponent Laboratories. This exemplar sample was maintained in our laboratories since receipt.

April 14, 2016 – Reference SEM microscopy of the exemplar sample was collected with a Zeiss Sigma VP-FEG SEM. Reference light microscopy was conducted with a Keyence VHX-600 digital microscopy system.

Apri1 17, 2016 – A reference FTIR spectra was obtained of the exemplar sample prior to exposure using a Thermo-Nicolet Continuum FTIR Microscope.

April 18, 2016 – The exemplar sample was mounted in a small clip and placed in the Q-Lab Q-Sun Xe-3 Xenon Test Chamber. The chamber was programmed per ASTM G 155 in the following exposure protocol:

> Chamber cyclic conditions were set to 4 hrs. “on”, at 340 nm wavelength, 1.10 W/m^2 irradiation at 63°C, and 35% RH using a Daylight filter set, followed by 1 hr. “off” (40°C and 35% RH).

May 11, 2016 – The sample was removed from the test chamber after 500 hours of exposure.

May 12, 2016 – FTIR spectra of the exemplar sample after 500 hours exposure was collected using a Thermo-Nicolet Continuum FTIR Microscope.

May 14, 2016 – SEM microscopy of the exemplar sample after 500 hours was collected with a Zeiss Sigma VP-FEG SEM. Light microscopy was collected with a Keyence VHX-600 digital microscopy system.

June 21, 2016 – The 500 hours Xenon exposed sample weighing 2.3 mg was placed in 2.3 ml DI H_2O in a Max Q 2000 orbital shaker at 80°C for 20 hrs. at 100 RPM.

June 22, 2016 – After removal from the shaker, the sample was blotted dry, allowed to equilibrate 1 hour at room temp (22°C) and an FTIR spectra was collected using a Thermo-Nicolet Continuum FTIR Microscope.

June 23, 2016 – The 2.3 mg sample after 20 hours/80°C in DI H_2O was immersed in 2.3 ml of 8.25% NaOCl and placed in a Max Q 2000 orbital shaker at 25°C for 30 minutes at 100 RPM. The sample was removed from the shaker, blotted dry and allowed to equilibrate overnight at 22°C

June 24, 2016 – The sample, after 20 hours/80°C in DI H_2O and 30 min./22°C in NaOCl, was analyzed with a Thermo-Nicolet Continuum FTIR Microscope.